REMARKS

Claims 15-23 are currently pending. Claims 15-23 stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement. The Examiner asserts that the claims contain subject matter not described in such a way as to enable one skilled in the art to use the invention. Applicants respectfully traverse this rejection for at least the reasons presented below.

It is well settled law that when a compound or composition claim is not limited by a recited use, any enabled use that would reasonably correlate with the entire scope of that claim is sufficient to preclude a rejection for nonenablement based on how to use. See the Manual of Patent Examining Procedure (MPEP) § 2164.01(c). Applicants respectfully submit that the specification sets forth a use for the claimed compositions of the inventions, and that this use is enabled by a teaching of how to perform the use, as indicated by a working example demonstrating that the use accomplishes its intended purpose.

The claims relate to chimeric fusion proteins. Claims 15-17 are directed towards chimeric fusion proteins comprising a bacteriorhodopsin protein amino acid sequence and at least a portion of a bovine rhodopsin intracellular loop 3. Claims 18-20 are directed towards polynucleotides that encode the claimed chimeric fusion protein and an archaebacterium composition comprising the polynucleotide that encodes the claimed chimeric fusion protein. Claim 21 is directed towards a method of making the claimed chimeric fusion proteins, and claims 22-23 are directed toward methods using the claimed chimeric fusion proteins to test a molecule for its ability to interact with the intracellular loop 3 of a G protein-coupled receptor. Claims 15-20 have no specifically claimed use, claim 21 has the claimed use of making the chimeric fusion protein, and claims 22-23 claim using the chimeric fusion proteins to test a molecule for its ability to interact with the intracellular loop 3 of a G protein-coupled receptor.

The specification indicates that the claimed chimeric fusion proteins may be used in assays to evaluate the role of G protein-coupled receptors in signal transduction. (See page 4, lines 28-32 of the specification.) The specification also indicates that the claimed intact bacteriorhodopsin/G protein-coupled receptor chimeric protein can be isolated in quantities sufficient to be used in high throughput assays of potential therapeutics, as well as to obtain information about the structure of the replacement loop. See page 4, lines 34-36 and page 5, lines 1-5 of the specification. One asserted use of the chimeric fusion proteins is in assays to

identify compounds that affect G protein-coupled receptors.

As described in the specification, such assays are useful in identifying compounds that may have utility in treating diseases associated with mutations that interfere with the ability of a G protein-coupled receptor to bind to extracellular ligands. Treatment of these diseases depends upon the development of pharmaceuticals capable of altering the activation of signaling pathways. See page 2, lines 21-37, and page 3, lines 1-24 of the specification. Applicants indicate that the presently claimed chimeric fusion proteins can be used in high throughput assays to help identify compounds that either enhance or reduce G protein interaction with a G protein-coupled receptor, thereby altering the activity of G proteins. One such activity is GDP-GTP exchange activity. Such activity is a useful step in identifying drugs which can be used to treat disease associated with mutations to G protein-coupled receptors.

Specification enables use by teaching a method of performing an assay and providing results showing the assay works.

The specification indicates a use for the claimed chimeric fusion proteins in an assay to test for compounds that can interact with the intracellular loop 3 region or affect GDP-GTP exchange activity, and specifically describes how to conduct such an assay. In addition, the specification presents results obtained using the assay. (See specification pages 23-27.) The specification demonstrates that the claimed chimeric fusion proteins were evaluated to determine the effect of the chimera on the rate of GDP-GTP exchange on transducin using a GTPγS uptake assay. The assay conditions were described (see page 23, lines 29-37 and page 24, lines 1-10) and the results shown (see page 24). Furthermore, using the assay, a compound known to inhibit transducin activation by rhodopsin (i.e., the high affinity analog SEQ ID NO:43), was in fact found to inhibit GDP-GTP exchange. (See page 25 of the specification.) In contrast, a random peptide sequence was used as a control did not inhibit GDP-GTP exchange. (See pages 25 and 26 of the specification.) The assay therefore provides both a protocol of how to conduct the assay using the claimed chimeric fusion proteins and results showing that the assay works for determining whether a compound has inhibitory effects on the GDP-GTP exchange. The Examiner has provided no arguments or evidence challenging the results of the assay provided in the specification.

However, the Examiner asserts that other data should have been provided to better demonstrate the ability of the presently claimed chimeric fusion proteins to assay for GDP-GTP exchange activity (e.g., GTPγS uptake results should have been expressed in pmols/min). The Examiner also asserts that large amounts of the presently claimed chimeric fusion proteins are needed to show GDP-GTP exchange activity. Such arguments, however, do not rebut the fact that an assay was taught and results were provided that showed the assay worked. The MPEP states:

> "A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." See MPEP § 2164.04

The Examiner has provided no arguments or evidence challenging the "objective truth" of the results provided by the described assay. The Examiner is simply stating his opinion that the data provided, while not incorrect or faulty, is not as valuable as other data might have been. The Examiner, therefore, does not question that the presently claimed compounds can be used in the assay disclosed, or that the assay shows GDP-GTP exchange activity, but rather questions the overall value of the data compared to other data often used to assess GDP-GTP exchange activity.

Applicants disagree with the Examiner's contention that results of assays provide data of "no practical use." The relative strength of the data itself, however, is irrelevant to the question of enablement of the use of the compounds. The Examiner's assertion that the assays using the compounds of the present invention are not of "great" use does not establish that the assays have **no** use. The overall value of the data is to be determined in the marketplace of ideas and research, not by the USPTO. It is enough that the specification of the application teaches a use of the compounds, and that the use is shown to be enabled. Applicants have provided both.

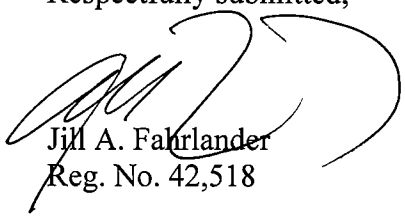
Conclusion

The specification of the application teaches that the claimed chimeric fusion proteins can be used in assays that can detect whether compositions have an effect on GDP-GTP exchange activity. The specification indicates that such assays are useful in identifying possible drugs that

can treat diseases associated with mutations in G protein-coupled receptors. The specification teaches an assay to detect the effect compositions have on GDP-GTP exchange activity, and provides results showing that such an assay works. Applicants submit, therefore, that the specification clearly provides both a use of the claimed compositions, and has enabled that use by demonstrating how to perform the assay and that the assay works. Furthermore, the Examiner has provided no arguments or evidence challenging the results of the assay provided in the specification. Applicants, therefore, respectfully submit that claims 15-23 are enabled for their use under 35 U.S.C. § 112, first paragraph.

In light of the foregoing, Applicants respectfully request withdrawal of the rejection and allowance of the claims. This response is being filed within three months of the statutory period for reply, so no fee is believed due in connection with this submission. However, if a fee is owed, please charge Deposit Account No. 50-0842 for such fee. Should Examiner Brannock feel that any other point requires consideration or that the form of the claims can be improved, he is invited to contact the undersigned at the telephone number provided below.

Respectfully submitted,



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